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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• Testing Tasks: This section measures the skills of Data Managers and involves creating test plans, generating test data, executing validation and user acceptance testing, and documenting results to ensure systems and processes perform reliably and according to specifications.
Topic 2	• Design Tasks: This section of the CCDM exam measures skills of Data Managers and covers how to design and document data collection instruments, develop workflows and data flows, specify data elements, CRF forms, edit checks, reports, database structure, and define standards and procedures for traceability and auditability.
Topic 3	• Data Processing Tasks: This section measures skills of Clinical Systems Analysts and focuses on handling, transforming, integrating, reconciling, coding, querying, updating, and archiving study data while maintaining quality, consistency, and proper privileges over the data lifecycle.
Topic 4	• Review Tasks: This section measures the skills of Data Managers and involves reviewing protocols, CRFs, data tables, listings, figures, and clinical study reports (CSRs) for consistency, accuracy, and alignment with data handling definitions and regulatory requirements.

Topic 5	• Coordination and Project Management Tasks: This domain evaluates the skills of a Clinical Systems Analyst in coordinating data management workload, vendor selection, scheduling, cross-team communication, project timeline management, risk handling, metric tracking, and preparing for audits.

Well-Prepared Free CCDM Dumps & Leading Offer in Qualification Exams & Updated CCDM: Certified Clinical Data Manager

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SCDM Certified Clinical Data Manager Sample Questions (Q148-Q153):

NEW QUESTION # 148
On a dose escalation study, the Data Manager notices one site has a much higher number of queries than other sites and most are older than 30 days. The Data Safety Monitoring Board will meet in three weeks. What should the Data Manager providing CRO oversight do?

- A. Call the site directly and ask the study coordinator about the concerns
- B. Ignore it for now and check back next week
- C. Notify the CRO's Clinical Leader about the concerns
- D. Consult the CRO's Lead Data Manager and the CRO's Project Leader

Answer: D

Explanation:
The correct action is to consult the CRO's Lead Data Manager and CRO's Project Leader (Option C) to ensure the issue is addressed through the appropriate oversight and escalation process.
According to the GCDMP (Chapter: Project Management and Communication), when a sponsor Data Manager identifies significant data management issues under CRO oversight - such as aging queries or site performance disparities - communication must follow the established governance and escalation pathway defined in the Scope of Work (SOW) and Data Management Plan (DMP).
Directly contacting the site (Option B) bypasses the CRO's chain of command and violates communication protocols. Notifying only the Clinical Leader (Option A) is insufficient, and ignoring the issue (Option D) jeopardizes the Data Safety Monitoring Board (DSMB) review timeline.
Therefore, Option C ensures a documented, collaborative approach to problem resolution within the contractual oversight structure.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 7.1 - Oversight of CRO Data Management Activities ICH E6 (R2) GCP, Section 5.2 - Contract Research Organization Responsibilities
FDA Guidance for Industry: Oversight of Clinical Investigations - Sponsor and CRO Roles and Communication Pathways

NEW QUESTION # 149
Which of the following processes is the most likely to remain in a study that utilizes electronic data capture?

- A. Retrieving case report forms
- B. Resolving queries
- C. Tracking case report forms
- D. Updating the in-house database

Answer: B

Explanation:
In studies utilizing Electronic Data Capture (EDC) systems, many traditional paper-based processes such as tracking and retrieving CRFs are eliminated or automated. However, query management and resolution remain essential because discrepancies, missing data, and protocol deviations still require clarification and correction, regardless of the data collection medium.

According to the GCDMP (Chapter: Data Validation and Cleaning), data queries are generated automatically or manually when inconsistencies are detected by edit checks. Sites must still respond to these queries electronically to ensure the integrity and completeness of data.

A and D are obsolete with EDC (no physical CRFs).

B refers to manual data entry updates, which are replaced by direct EDC entry.

C (Resolving queries) continues as a key part of the data management workflow, even in fully electronic environments.

Thus, option C is correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 5.4 - Query Generation and Resolution in EDC Systems ICH E6(R2) GCP, Section 5.5.3 - Data Review and Query Resolution Requirements FDA 21 CFR Part 11 - Electronic Records: Audit Trails and Query Documentation C

NEW QUESTION # 150

A Data Manager is importing lab data for a study. The lab data and the associated audit trail is kept at the central lab. What is necessary to maintain traceability of the transferred data at the Data Manager's location?

- A. Making changes only after data have been imported
- B. Making changes only for exceptions
- C. Maintaining a copy of the data as received
- D. Making changes only on the copy of the received data

Answer: C

Explanation:

Maintaining traceability of external data imports (such as laboratory results) is a fundamental principle of clinical data management. According to the GCDMP (Chapter: External Data Transfers and Integration), Data Managers must retain an unaltered copy of the raw data exactly as received from the vendor.

This archived version serves as a reference for:

Data provenance verification,

Audit trail review, and

Discrepancy resolution between vendor and study database.

Since the central lab maintains its own audit trail, the Data Manager's responsibility is to preserve the original data transmission file before applying transformations, merges, or validations.

Options A, C, and D describe procedural safeguards but do not meet the regulatory requirement of traceable data lineage. Only option B (Maintaining a copy of the data as received) ensures compliance with ICH E6(R2) and FDA 21 CFR Part 11 standards for data traceability and integrity.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: External Data Transfers and Integration, Section 5.2 - Data Traceability and Version Control ICH E6(R2) GCP, Section 5.5.3 - Data Integrity and Source Data Verification FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.4 - Source Data Traceability and Archiving

NEW QUESTION # 151

Which Clinical Study Report section would be most useful for a Data Manager to review?

- A. Clinical narratives of adverse events
- B. Description of statistical analysis methods
- C. Enumeration and explanation of data errors
- D. Rationale for the study design

Answer: C

Explanation:

The section of the Clinical Study Report (CSR) that is most useful for a Data Manager is the one that includes the enumeration and explanation of data errors. This section provides a summary of the data quality control findings, including error rates, missing data summaries, and any issues identified during data review, validation, or database lock.

According to the GCDMP (Chapter: Data Quality Assurance and Control), post-study reviews of data errors and quality findings are essential for evaluating process performance, identifying recurring issues, and informing continuous improvement in future studies.

Other sections, such as clinical narratives (A) or statistical methods (C), are outside the core scope of data management responsibilities. The data error enumeration section directly reflects the quality and integrity of the data management process and is

therefore the most relevant for review.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 6.4 - Quality Reporting and Error Analysis ICH E3 - Structure and Content of Clinical Study Reports, Section 14.3 - Data Quality Evaluation

NEW QUESTION # 152
Which of the following ensures that the trials are conducted and the data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s)?

- A. Statistical Analysis Plan (SAP)
- B. CRFs
- C. Standard Operating Procedures (SOP)
- D. Data Management Plan (DMP)

Answer: C

Explanation:
Standard Operating Procedures (SOPs) are formal, controlled documents that define standardized processes to ensure clinical trials are conducted in compliance with Good Clinical Practice (GCP), the study protocol, and regulatory requirements (such as ICH and FDA).
According to Good Clinical Data Management Practices (GCDMP) and ICH E6(R2) GCP, SOPs are fundamental to quality management systems. They describe how tasks are performed, ensuring consistency, accountability, and traceability across all studies and team members. Proper adherence to SOPs guarantees that data are accurately generated, documented, and reported in compliance with ethical and regulatory standards.
Other options serve different purposes:
SAP (B) defines statistical methodology, not compliance control.
DMP (C) focuses on study-specific data handling, not organizational compliance.
CRFs (D) are tools for data collection but do not enforce compliance by themselves.
Therefore, option A (SOP) is correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Quality Management and Compliance, Section 5.1 - Role of SOPs in Regulatory Compliance ICH E6(R2) GCP, Section 2.13 and 5.1.1 - Quality Management Systems and SOP Requirements FDA 21 CFR Part 312.50 - Sponsor Responsibilities and Compliance Systems

NEW QUESTION # 153
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